Notice of Allowability	Application No.	Applicant(s)	
	10/088,320	COCOLA ET AL.	
	Examiner	Art Unit	
	Steven S. Paik	2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the After Final Amendment filed July 2, 2004*.

2. ☒ The allowed claim(s) is/are *1-3,5-12 and 21-28*.

3. ☒ The drawings filed on *14 March 2002* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20040722* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Steven S. Paik
Examiner
Art Unit: 2876

DETAILED ACTION

Response to Amendment

1. Receipt is acknowledged of the Amendment filed July 2, 2004. The amendment includes amended claims 23 and 25 and cancelled claims 4 and 13-20.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. John James McGlew on July 22, 2004.

The application has been amended as follows:

Re claim 10, the applicant has agreed to replace the word, "it" in lines 14 and 15 with -- said at least one analyzer --.

IN THE CLAIMS:

1. (Previously Presented) A method for data management for an analytical laboratory, the method comprising the steps of:

providing a plurality of containers for the laboratory analysis of biological specimens, each container being associated with a unique identification code of said container and having a marking including said unique identification code applied to said container during production or packaging of said container;

associating a patient code with a patient to be subjected to analysis;

for each container used for said patient, generating in a data processing system a combination of said patient code and said unique identification code of the corresponding container;

carrying out, by means of at least one analyzer, at least one analysis on the container or containers used for said patient, the analyzer entering the results of said analysis, combined with the unique identification code of the container or containers, into the data processing system.

2. (Previously Presented) The method according to Claim 1, comprising the steps of:

generating a patient code for at least one patient on whom at least one analysis is to be carried out and storing said patient code in a data processing system;

placing a biological specimen from said patient in said at least one container;

carrying out at least one analysis of said specimen in at least one analyzer, the analyzer reading the unique identification code of said container and entering into said data processing system the results of the analysis combined with the unique identification code of said container;

using said data processing system to associate the results of the analysis or analyses with the patient code, and then with the patient identified by said patient code, by means of the combination of the patient code with the unique identification code.

3. (Previously Presented) The method according to Claim 1, in which said unique identification code is placed on the corresponding container in a machine readable format.

4. (Canceled)

5. (Previously Presented) The method according to Claim 1, in which said patient code is placed on a medium in a machine-readable formal.

6. (Previously Presented) The method according to Claim 3, in which the combination of the patient code with the unique identification code is generated by the sequential reading by an automatic reading instrument of the patient code and the unique identification code, or vice versa.

7. (Previously Presented) The method according to Claim 1, in which said patient code and said unique identification code are reproduced as bar codes and are optically read to produce said combination.

8. (Previously Presented) The method according to Claim 1, in which said patient code is generated by a central computer of said data processing system; the combination of the patient code with the unique identification code is carried out by means of a unit of said data processing system other than said central computer; and the result of the analysis, associated with the patient code, is sent to said central computer.

9. (Previously Presented) The method according to Claim 1, in which said patient code is generated by a central computer of said data processing system; the combination of the patient code with the unique identification code is carried out by means of a unit of said data processing system other than said central computer; and the result of the analysis, associated with the unique identification code of the container, is sent to said central computer, the central computer being programmed to associate with the result of the analysis the data relating to the patient to whom said result relates.

10. (Currently Amended) A data processing system for data management in an analytical laboratory, the system comprising, in combination,

a central electronic computer, for acquiring the data on patients on whose biological specimens the analyses are to be carried out, and for generating a patient code for each patient acquired;

means for acquiring a unique identification code associated with each container of a plurality of containers for laboratory analysis of biological specimens;

a marking with said unique identification code, said marking being applied to said container during production or packaging of the container;

means for combining each of said acquired unique identification codes with a corresponding patient code to form combined database on said unique identification code and said patient code;

at least one analyzer with means for reading the unique identification codes associated with the containers which are placed in ~~it~~ said at least one analyzer, said analyzer carrying out at least one analysis on a biological specimen contained in the containers placed in ~~it~~ said at least one analyzer and supplying to said electronic computer the result of the analyses carried out, combined with data capable of associating said result with the patient to whom the biological specimen belongs based on said combined data.

11. (Previously Presented) The system according to Claim 10. comprising means for receiving from said at least one analyzer the result of said at least one analysis combined with the unique identification code of the container in which the analyzed biological specimen is placed; said means being programmed to associate said result with the patient code relating to the unique identification code combined with the result of the

analysis, to send the result of the analysis combined with the patient code to said central electronic computer.

12. (Previously Presented) The system according to Claim 10, in which the result of the analysis, combined with the unique identification code of the corresponding container, is sent to said central computer, the central computer being programmed to associate, by means of the combination of the patient code with the unique identification code, each unique identification code - and consequently the result of the analysis - with the patient code of the patient whose biological specimen is contained in the container identified by said unique identification code.

13 - 20 (Canceled)

21. (Previously Presented) The method according to Claim 1, further comprising;

connecting a means to each container for determining an expiry date of the respective container.

22. (Previously Presented) The system according to Claim 10, further comprising:

means connected with each container for determining an expiry date of the respective container.

23. (Previously Amended) An analytical laboratory data management method comprising the steps of:

generating unique identification codes;

providing a plurality of containers for the laboratory analysis of biological specimens;

associating each of said containers with one of said unique identification codes and applying a marking including said unique identification code to the associated container during production or packaging of the container at a first location;

generating patient codes with a host computer or providing as input into the host computer the generated patient codes;

associating each patient code with an individual patient to be subjected to analysis;

providing, at a second location, a biological specimen from the individual patient with the associated patient code in the container with said marking including said unique identification code;

providing correlation data, based on a combination of said patient code and the marked said unique identification code of the corresponding container for which the biological specimen has been or will be provided, by reading or receiving said patient code and reading the marked said unique identification code of the corresponding container having the biological specimen, said correlation data being provided to a device separate from said host computer;

providing an analyzer for analysis of the biological specimen;

carrying out at least one analysis on the container, with the unique identification code having the biological specimen, using the analyzer to provide results of the analysis associated with the unique identification code;

associating the results of the analysis with the patient code at the device separate from the host computer based on the correlation data; and

sending the results of the analysis and associated patient code to the host computer.

24. (Previously Presented) The method according to Claim 23, further comprising: connecting a means to each container for determining an expiry date of the respective container.

25. (Previously Amended) An analytical laboratory data management method comprising the steps of:

generating unique identification codes;

providing a plurality of containers for the laboratory analysis of biological specimens;

associating each of said containers with one of said unique identification codes and applying a marking including said unique identification code, to the associated container during production or packaging of the container at a first location;

generating patient codes with a host computer or providing as input into the host computer the generated patient codes;

associating each patient code with an individual patient to be subjected to analysis;

providing, at a second location, a biological specimen from the individual patient with the associated patient code in the container with said marking including said unique identification code;

providing correlation data based on a combination of said patient code and the marked said unique identification code of the corresponding container for which the biological specimen has been or will be provided, by reading or receiving said patient

code and reading the marked said unique identification code of the corresponding container having the biological specimen;

providing an analyzer for analysis of the biological specimen;

carrying out at least one analysis on the container, with the unique identification code having the biological specimen, using the analyzer to provide results of the analysis associated with the unique identification code;

sending the results of the analysis associated with the unique identification code to the host computer; and

associating the results of the analysis with the patient code at the host computer based on the correlation data.

26. (Previously Presented) The method according to Claim 25, further comprising:

connecting a means to each container for determining an expiry date of the respective container.

27. (Previously Presented) A set of containers for laboratory analysis of biological specimens, each container of the set comprising:

a container body;

a marking or label connected to said container body and having or embodying a machine-readable identification code that is unique to said container body relative to other identification codes of the set of containers, said marking or label with said machine-readable identification code being associated with said container body and applied to said container body during production or packaging of said container body; and

means connected with said container body during production or packaging of said container body for determining an expiry date.

28. (Previously Presented) The container according to Claim 27, wherein said identification code is a bar code.

Allowable Subject Matter

3. Claims 1-3, 5-12, and 21-28 are allowed.

The following is an examiner's statement of reasons for allowance: the cited prior arts of the record, Chaffin, III et al. (US 3,831,006); Knepple et al. (WO 99/41014) and Carr et al. (US 5,888,825) taken alone or in combination of other references do not teach, disclose, or fairly suggest the claimed method and system for data management for an analytical laboratory comprising, among other things and steps, providing a plurality of containers for the laboratory analysis of biological specimens each container being associated with a unique identification code of said container and having a mark including said unique identification code applied to said container during production or packaging of the container. Upon careful consideration of applicant's remark, amendment, and updated prior art search, claims 1-3, 5-12, and 21-28 appear to be in condition for allowance over the prior art made of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven S. Paik whose telephone number is 571-272-2404. The examiner can normally be reached on Mon - Fri (5:30am-2:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on 571-272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven S. Paik
Examiner
Art Unit 2876

ssp